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10/538,236	06/09/2005	Takashi Ishizuka	1369.45130X00	8730

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EXAMINER	
ELHASSAN, AHMED A	

ART UNIT	PAPER NUMBER
4138	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,236	ISHIZUKA ET AL.	
	Examiner	Art Unit	
	AHMED ELHASSAN	4138	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 June 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/09/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every features of the invention specified in the claims, or the features canceled from the claim(s). No new matter should be entered. Regarding claimed subject matter of claim 11;

a. The "spring mechanism" is not shown.

b. Fixing member not distinguishable from "height adjustment jig" in FIG. 2.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p) (5) because they include the following reference character(s) not mentioned in the description: "206" in FIG. 3. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 -20 recite the limitation "measuring probe portion" in line 7 of parent claim 18. There is insufficient antecedent basis for this limitation in the claim. For claims 18-20, for the purposes of this first office action, the phrase" measuring probe portion" is interpreted to mean any region of the probe's outermost surface which contacts the patient.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1- 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite part of the human body "subject" in combination with the device, e.g. (claim 1: "attached to subject"). It has been held that a claim directed to, or including within its scope, a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of limited, but exclusive property right in a human being is prohibited by the constitution. *In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).* For examination purposes, all claims will be considered as if such limitations involving the combination with a human were not present.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3, 4, 5, 7, 9, 10, 14, 15, 17, 18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Jobsis et al. (US4321930).

Regarding claim 1, Jobsis (FIG 1- 8) shows a measuring probe (abs. line 3) comprising:

A holder portion (abs. line 1) attached to the subject; and an optical fiber ("fiber optic cable" FIG. 3 & col. 12 lines 2-3) for at least one of irradiation and detection(Fig. 1) whose distal end portion on a subject side is retained by the holder portion (ensemble of parts 65,66, 75 & 60 in Fig. 1) , where in the optical fiber is led out from a side surface of the holder portion and is bent(Fig. 8) inside the holder portion such that the distal end portion is directed to the subject when the holder portion is attached to the subject (Fig. 1).

Regarding claim 3, Jobsis as applied to claim 1, shows a "holder portion (FIG. 1) that has a first member to be brought into contact with the subject (FIG. 1, No. 60) and a second member combined with the first member (FIG. 1, No. 75).

Regarding claim 4, Jobsis as applied to claim 3, shows a measuring probe wherein the first member (FIG. 1, No. 60)is more flexible than the second member, and the second member is more rigid than the first member (FIG. 1, No. 75).

Regarding claim 5, Jobsis as applied to claim 3, shows a measuring probe wherein a protecting groove, into which the optical fiber is inserted (FIG. 8), is formed in at least one of the first member (FIG. 1, No. 75) and the second member.

Regarding claim 7, Jobsis as applied to claim 1, shows a measuring probe wherein a space portion for accommodating the bent portion of the optical fiber is provided inside the holder portion (FIG. 7 & 8).

Regarding claim 9, Jobsis as applied to claim 1, shows a measuring probe wherein an optical fiber fixing member for fixing the distal end portion of the optical fiber (part no. 80 a, FIG 4) is arranged in the holder portion (hole 80, FIG. 5)

Regarding claim 10, Jobsis discloses (FIG. 12) a measuring probe wherein a space portion for accommodating the bent portion of the optical fiber and the optical fiber fixing member (FIG. 12, member No. 110) is provided in the holder portion, and wherein a diameter of the space portion is of the same size as an outer peripheral diameter of the optical fiber fixing member (member 80 'a' fits into space portion, FIG12).

Regarding claim14, Jobsis probe as applied to claim 1, already shows a measuring probe comprising a curving means provided on the holder portion, for maintaining the holder portion in a configuration curved along the subject (Jobsis; FIG. 1, patient side wall of No. 65).

Regarding claim 15, Jobsis as applied to claim14, shows a probe wherein the curving means (Jobsis; FIG. 1, No. 65) is mounted to the subject side of the holder portion (FIG. 1) and is a base plate curved in advance (lower curved edge, FIG. 5)

Regarding claim 17, Jobsis discloses a measuring probe wherein the curving means (part causes probe to conform to body contour; module 75 FIG. 1 & col. 9, line 17) is provided with a connecting portion (FIG. 1 No. 66) for connection with an adjacent curving means (elastic strap, FIG. 1, No. 60 & col. 8 line 50-54).

For the purposes of this first office action the word "holder portion", is interpreted, in claims 18-20, to mean any region of the front surface where the probe touches the patient.

Regarding claim 18, Jobsis discloses a living body (abs. lines 5-6) optical measuring device (col. 14, lines 15-16) comprising a measuring probe (FIG. 1) having a plurality of optical fibers (FIG. 3) that irradiate a subject with measurement light and receive the measurement light returning from the subject, the measuring probe being attached to the subject (FIG. 3), wherein the optical fibers are led out from a side surface of the measuring probe (FIG. 1 & 3) and are bent inside the measuring probe portion (FIG. 7 & 8) such that their distal end portions are directed towards the subject when the measuring probe is attached to the subject (FIG. 1).

Regarding Claim 20 Jobsis further discloses a living body optical measuring device as applied to claim 18, further including a fastening fixing member ("strap", col. 3, line 40) which is put on the subject from above the measuring probe (col. 8, lines 55-58 & FIG. 1) so as to surround the subject ("wrapped", col. 3, line 40) and which prevents the measuring probe from being detached ("attachment", col. 8, line 55) from the subject (FIG. 3).

6. Claims 1, 7, and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Lewandowski (US 6,839,583).

Regarding claim 1, Lewandowski (FIG 1- 8) shows a measuring probe (col. 2, line 36) comprising: A holder portion attached to the subject (FIG. 5 & col. 2 line 1); and an optical fiber (col. 2 line 39 & FIG. 3, No. 14) for at least one of irradiation and detection (FIG. 3, No. 16 & 18) whose distal end portion (Fig. 3 No. 16 & 18) on a subject side is retained by the holder portion, where in the optical fiber is led out from a side surface (surface where bundle No. 24 exits) of the holder portion and is bent (Fig. 3) inside the holder portion such that the distal end portion is directed to the subject when the holder portion is attached to the subject (Fig. 3 & col. 2 line 1).

Regarding claim 7, Lewandowski as applied to claim 1, shows a measuring probe wherein a space portion for accommodating the bent portion of the optical fiber is provided inside the holder portion (space containing optical fibers 24, 14, 16 & 18 in FIG. 3)

Regarding claim 8 Lewandowski discloses a measuring probe wherein the holder portion has a first member to be brought in contact with the subject (Fig. 4, insert 12),

and a second member (Fig. 4, housing 20) combined with the first member, and wherein the space portion is formed by combining recesses (space containing optical fibers 24, 14, 16 & 18 in FIG. 3) respectively provided in the first and second members.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jobsis in view of Brossia et al (4,851,817) and Hok (US 5786592).

Regarding claim 2, Jobsis lacks a measuring probe wherein an outer peripheral coating is removed from a bent portion of the optical fiber inside the holder portion.

1) Brossia teaches (fig. 2 & col. 4 lines 5-11) a measuring probe wherein an outer peripheral coating is removed from a bent portion of the optical fiber.

2) Hok teaches a measuring probe ("sensor", col.1, line 67) wherein a bent portion of the optical fiber (FIG. 1, "7a" & "7b") is inside the holder portion (FIG. 1, "8" & "9").

It would have been obvious to one of ordinary skill in the art at the time of the invention to 1) modify Hok measuring probe by Brossia's teaching of removing the peripheral coating from a bent portion of the optical fiber inside the holder portion, in order to improve measurement by precluding transfer of a portion of light through, 2) further modify Jobsis with Brossia-Hok teaching of removing the outer peripheral coating from the bent portion of the optical fiber inside the holder portion, also with the same motivation.

Regarding claim 12, Jobsis lacks: an optical fiber protecting member for protecting the bent portion of the optical fiber is arranged inside the holder portion.

Brossia teaches a measuring probe wherein an optical fiber protecting member ("protective sheath No. 27", FIG. 2 & col. 3, line 34) for protecting the bent portion of the optical fiber (unexposed bent portions of optical fiber still covered and protected by sheath No. 27, FIG. 2) is arranged inside the holder portion (sheath No. 27 is arranged inside holder portion; FIG. 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Jobsis with an optical fiber inside –the-holder protecting member for protecting the bent portion of the optical fiber, in view of Brossia, with the motivation to provide extra protection for the bent portion of the optical fiber inside the holder.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jobsis in view of Jobsis (US 4510938).

Jobsis '930 lacks that the measuring-probe holder portion is provided with a through-hole through which the distal end portion of the optical fiber is exposed and an annular protrusion protruding so as to surround the distal end portion of the optical fiber.

Jobsis '938 teaches a measuring-probe holder portion (FIG. 1) provided with a through-hole (FIG. 7, aperture 73) through which the distal end portion of the optical fiber (FIG. 6 terminal end 79) is exposed (FIG. 6, optical face No. 80) and an annular protrusion (FIG. 6, No. 100) protruding so as to surround the distal end portion of the optical fiber.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Jobsis '930 holder portion with through-hole through which the distal end portion of the optical fiber is exposed and an annular protrusion protruding so as to surround the distal end portion of the optical fiber, in view of Jobsis '938 with the motivation to ensure that there is no gap between the fiber optic and the subject's measured body part, furthermore direct fiber-body contact and annular structures minimize unwanted scattering.

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lewandowski in view of Mannschke (US 4,362,360).

Lewandowski probe as applied to claim 8 lacks an optical fiber fixing member having a spring mechanism which extrudes the optical fiber by a minute amount to the exterior of the holder portion while retaining the optical fiber.

Mannschke teaches an optical fiber fixing member with a spring mechanism that moves, i.e. extrudes, the optical fiber by a minute amount to the exterior of the holder portion while retaining the optical fiber (col. 3, lines 40-46) to align the fiber optic.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Lewandowski, with optical fiber fixing member with a spring mechanism capable of extruding the optical fiber by a minute amount to the exterior of the holder portion while retaining the optical fiber, in view of Mannschke to align the fiber optic.

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jobsis in view of Mannschke.

Regarding claim 13, Jobsis as applied to claim 1, lacks a height adjustment jig arranged inside the holder portion for adjusting the amount by which the optical fiber protrudes from the holder portion.

Mannschke teaches a means capable of being fitted inside the holder portion for adjusting the amount by which the optical fiber protrudes from the holder (col. 3, lines 40-46)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Jobsis with a height arrangement inside the holder portion, in view of Mannschke, to align the fiber optic

11. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jobsis in view of Mannheimer (US 5,842,982).

Jobsis probe as applied to claim 14 lacks a measuring probe wherein the curving means is replaceable with respect to the holder portion.

Mannheimer teaches a measuring probe wherein the curving means (heel pad shown in FIG. 6) is replaceable with respect to the holder portion (col. 2, lines 26-27). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Jobsis probe with a replaceable Jobsis-curving-means (i.e. strap), in view of Mannheimer, with the motivation to improve hygiene and reduce risk of spreading disease among possibly multiple users of the same curving patient-contacting means (i.e strap) of the same probe.

12. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jobsis in view of Pewzner et al. (US 7,130, 672).

Jobsis lacks a plurality of holder portions, wherein optical fibers are arranged at intervals and the optical fibers are led out from the side surface of the holder portion. Pewzner teaches a plurality of holder portions (Sheet 5, FIG. 4a; different regions of the front contact surface of probe No. 2 where optical fibers No. 201, 202 & 203 are organized), wherein optical fibers are arranged at intervals (spaces between optical

fibers, Sheet 5, FIG. 4a) and the optical fibers are led out from the side surface of the holder portion (tube No. 208, Sheet 3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Jobsis with holder portions wherein optical fibers are arranged at intervals, and the optical fibers are led out from the side surface of the holder portion to minimize entanglement, with the motivation to minimize analyte concentration error by sampling a bigger uniform area of the patient body.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AHMED ELHASSAN whose telephone number is (571)270-7390. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Melba Bumgarner can be reached on 571-272-4709. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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